IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

WALGREEN CO.,	§	
	§	
Plaintiff,	§	
	§	
v.	§	Case No. _____
	§	
U.S. DRUG ENFORCEMENT ADMINISTRATION; ANNE MILGRAM, in her official capacity as Administrator of the Drug Enforcement Administration; U.S. DEPARTMENT OF JUSTICE; and MERRICK B. GARLAND, in his official capacity as Attorney General of the United States,	§	
	§	
Defendants.	§	

COMPLAINT

Plaintiff Walgreen Co. ("Walgreens") brings this action for equitable relief against defendants the United States Drug Enforcement Administration ("DEA"); Anne Milgram, in her official capacity as Administrator of the DEA; the United States Department of Justice ("DOJ"); and Merrick Garland, in his official capacity as Attorney General of the United States (together, "Defendants").

Walgreens challenges Defendants' imposition of new rules governing how pharmacies dispense controlled substances. Not only are these rules arbitrary and capricious but, because they add content to the legal norms governing dispensing of prescriptions, they constitute final agency action requiring notice-and-comment rulemaking under the Administrative Procedures Act ("APA"). Because that required rulemaking never occurred, the rules are unlawful and must be set aside.

INTRODUCTION

1. The federal Controlled Substances Act ("CSA") and its implementing regulations establish a comprehensive regulatory regime governing the manufacturing, distributing, and dispensing of controlled substances in the United States.

2. This regulatory regime strikes a careful balance between satisfying the legitimate medical needs for controlled substances and protecting against illegal diversion for illegitimate use. As the Supreme Court explained, prescribing controlled substances is not "inherently illegitimate; we expect, and indeed usually want, doctors to prescribe the medications that their patients need." *Ruan v. United States*, 597 U.S. 450, 459 (2022).

3. DEA has acknowledged the important dual goals served by its regulations. Thus, it has explained that, while working to prevent diversion, it must take "just as seriously its obligation to ensure that there is no interference with the dispensing of controlled substances to the American public in accordance with the sound medical judgment of their physicians." *Dispensing Controlled Substances for the Treatment of Pain*, 71 Fed. Reg. at 52,719-20 (Sept. 6, 2006).

4. To avoid interfering with the American public receiving controlled substances prescribed by their physicians, DEA regulations place only limited obligations on pharmacists to refuse to fill prescriptions. A pharmacist may not "knowingly fil[l]" an invalid prescription. 21 C.F.R. § 1306.04(a). If a pharmacist is uncertain (or even suspicious) as to a prescription's validity, the pharmacist does not face penalties under the CSA for filling it.

5. The limited scope of the duties imposed on pharmacists was the product of a conscious decision by regulators. During promulgation of the first regulations under the Comprehensive Drug Abuse Prevention and Control Act of 1970, the "National Association of Retail Druggists objected to the responsibility placed upon a pharmacist [by the draft regulation]

to determine the legitimacy of a prescription." In response, DEA[1] revised the final language of the regulations "to require ***knowledge***" that the prescription was illegitimate. *Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970*, 36 Fed. Reg. 7776, 7777 (Apr. 24, 1971) (emphasis added). That regulatory language—and its knowledge requirement—has survived unchanged to this day.

6. In recent years, however, DEA has upset this careful regulatory balance by adopting new rules that impose precisely the obligation "to determine the legitimacy of a prescription" that was rejected in notice-and-comment rulemaking in 1971.

7. Now, DEA says that "[a] pharmacist must resolve all 'red flags' before the dispensation of any prescription drugs." Press Release, Drug Enforcement Administration, Federal Court Orders San Antonio-Area Pharmacy and Pharmacist to Pay $275,000 Civil Penalty in Case Alleging Unlawful Opioid Distribution (Oct. 11, 2023), https://www.dea.gov/press-releases/2023/10/11/federal-court-orders-san-antonio-area-pharmacy-and-pharmacist-pay-275000.

8. In other words, DEA now mandates that pharmacists must "ensure the legitimacy of prescriptions" before filling them. Press Release, Department of Justice, Federal Court Restrains Tampa Pharmacy and Two Individuals From Dispensing Opioids or Other Controlled Substances (Jan. 29, 2021), https://www.justice.gov/opa/pr/federal-court-restrains-tampa-pharmacy-and-two-individuals-dispensing-opioids-or-other.

9. Separately, DEA has announced that pharmacies must "block" all controlled substance prescriptions from "problematic" (and yet duly licensed and DEA-registered) prescribers and that pharmacies violate the CSA when their pharmacists fill any controlled

[1] Technically, the predecessor of DEA, the Bureau of Narcotics and Dangerous Drugs.

substance prescription from such a prescriber, regardless of the legitimacy of the particular prescription and regardless of the knowledge of the filling pharmacist.

10. The failure to follow these new rules can result in the imposition of severe criminal and civil penalties on both a pharmacist and pharmacy and the revocation of a pharmacy's DEA registration authorizing it to dispense controlled substances.

11. These new rules—which DEA and DOJ are now enforcing against regulated entities—mark the culmination of agency decision-making and impose new duties and obligations on regulated entities. They constitute final agency action and legislative rules under the APA.

12. Because DEA has promulgated new legislative rules, which add content to legal norms and create new duties, without following the required process for notice-and-comment rulemaking, its new rules are unlawful under the APA and must be set aside.

JURISDICTION AND VENUE

13. This Court has jurisdiction over the subject matter of this civil action because the claims arise under the laws of the United States. 28 U.S.C. §1331; 28 U.S.C. §2201: 5 U.S.C. §§701-706.

14. This Court is authorized to award the requested relief under 5 U.S.C. §706; 28 U.S.C. §1361; and 28 U.S.C. §§2201-02.

15. Venue is appropriate in the Eastern District of Texas and in the Tyler Division pursuant to 28 U.S.C. § 1391(e). This statute provides that a suit may be brought where "a substantial part of the events or omissions giving rise to the claim occurred, or a substantial part of property that is the subject of the action is situated." *Id*. Walgreens is registered with the Texas Secretary of State to do business in the State of Texas. Because Walgreens maintains numerous store locations in the Eastern District of Texas, including approximately 40 or more locations

within the Tyler Division, and at each of those locations employs multiple pharmacists subject to the challenged regulatory rules in this Division, the criteria are met.

PARTIES

16. Plaintiff Walgreen Co. is an Illinois corporation that has its principal place of business in Deerfield, Illinois.

17. Defendant DEA is an agency of the United States and a component law enforcement agency under DOJ. 12 U.S.C. § 5491(a).

18. Defendant Anne Milgram is the Administrator of the DEA. Administrator Milgram is sued in her official capacity.

19. Defendant DOJ is an agency of the United States. 12 U.S.C. § 5491(a).

20. Defendant Merrick B. Garland is the Attorney General of the United States. Attorney General Garland is sued in his official capacity.

ALLEGATIONS

I. The CSA Governs the Distribution and Dispensing of Prescription Opioid Medications in the United States.

21. Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801, *et seq.*, commonly known as the Controlled Substances Act, establishes a comprehensive regime governing controlled substances. Controlled substances are pharmaceutical and non-pharmaceutical substances deemed to pose a risk of abuse and dependence. 21 U.S.C. §§ 802(6), 811.

22. The CSA lays the framework for the classification of controlled substances, 21 U.S.C. §§ 811-14; provides for the registration of manufacturers, distributors, prescribers, and dispensers of controlled substances, *id.* §§ 822-32; and establishes penalties for the production, distribution, and possession of controlled substances outside of the registration system, *id.*

§§ 841-65; *see also* 21 U.S.C. § 802(10) (defining dispensing to include prescribing controlled substances).

23. The CSA and its implementing regulations also authorize DEA to set aggregate production quotas and individual manufacturing quotas for each registrant manufacturing Schedule I or II drugs. 21 U.S.C. §826(b); 21 C.F.R. § 1303.12. This quota system is based on DEA's assessment of the legitimate medical needs for controlled substances, facilitating accounting, ensuring sufficient amounts of each controlled substance are in circulation, and acting as a preventative measure against diversion by enabling DEA to limit the quantities of controlled substances introduced into the supply chain.

24. Every person who manufactures, distributes, prescribes, or dispenses any controlled substance, or proposes to do so, must obtain a registration from DEA. 21 U.S.C. § 822; 21 U.S.C. § 802(10).

25. A registrant may only manufacture, distribute, or dispense controlled substances "to the extent authorized by their registration and in conformity with the other provisions of this subchapter." 21 U.S.C. § 822(b).

26. Thus, the CSA requires pharmacies that dispense controlled substances, like Walgreens, to obtain registrations from DEA. *Id.* § 822(a). The CSA defines "dispense" to include "deliver[ing] a controlled substance to an ultimate user . . . pursuant to the lawful order of . . . a practitioner." *Id*. § 802(10).

27. An agent or employee of a dispenser of controlled substances is not required to have a separate DEA registration "if such agent or employee is acting in the usual course of his business or employment." *Id*. § 822(c)(1). Walgreens employs pharmacists, who dispense controlled substances by filling valid prescriptions.

28. DEA may deny an application for registration or revoke an existing registration if the registration would be "inconsistent with the public interest." 21 U.S.C. §§ 824(a)(4), 823(f).

29. Violation of the CSA can result in severe civil and criminal penalties. 21 U.S.C. § 841 (criminal penalties); 21 U.S.C. § 842(c)(1)(A) (civil penalties); 28 C.F.R. § 85.5 (civil penalties).

II. The CSA and its Implementing Regulations Strike a Careful Balance Between Preventing Diversion and Ensuring that There Is No Interference with the Dispensing of Controlled Substances to the American Public in Accordance with the Sound Medical Judgment of Their Physicians.

30. The CSA and its implementing regulations strike a careful balance between preventing diversion and ensuring that there is no interference with the professional medical judgment of physicians prescribing controlled substances for their patients. *See Dispensing Controlled Substances for the Treatment of Pain*, 71 Fed. Reg. at 52,719-20 (Sept. 6, 2006).

31. The CSA grants the Attorney General authority to "promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter." 21 U.S.C. § 871(b). The Attorney General has delegated that authority to the Administrator of DEA. 28 C.F.R. § 0.100(b). Pursuant to that authority, DEA and its predecessor agencies have promulgated rules and regulations implementing the CSA.

32. Under these rules and regulations, a prescription for a controlled substance may only be issued by a practitioner who is: "(1) [a]uthorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession and (2) [e]ither registered or exempted from registration." 21 C.F.R. § 1306.03(a).

33. A prescription for a controlled substance is valid if it is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional

practice." 21 C.F.R. § 1306.04(a). "An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of [21 U.S.C. § 829]." 21 C.F.R. § 1306.04(a).

34. For a prescription to be deemed not to have been issued in the usual course of professional treatment, the doctor must not have been acting as a medical professional. *See United States v. Feingold*, 454 F.3d 1001, 1008 (9th Cir. 2006); *United States v. Chube II*, 538 F.3d 693, 698 (7th Cir. 2008); *United States v. Alerre*, 430 F.3d 681, 691 (4th Cir. 2005) (referring to a physician "cloaking drug deals under the guise of a professional medical practice").

35. While "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner," "a corresponding responsibility rests with the pharmacist who fills the prescription." 21 C.F.R. § 1306.04(a). A pharmacist must not "knowingly fil[l]" an order "purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research." 21 C.F.R. § 1306.04(a). A pharmacist "knowingly filling" such a prescription is "subject to the penalties provided for violations of the provisions of law relating to controlled substances." 21 C.F.R. § 1306.04(a).

36. The source of this knowledge requirement is found in the record of the rulemaking process. The initial notice of proposed regulations implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970 did not include a knowledge requirement:

> An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person filling such a prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

36 Fed. Reg. 4928, 4948 (Mar. 13, 1971).

37. During the notice-and-comment period, the "National Association of Retail Druggists objected to the responsibility placed upon a pharmacist [by this draft regulation] under § 306.04 to determine the legitimacy of a prescription." *Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970*, 36 Fed. Reg. 7776, 7777 (Apr. 24, 1971). The Bureau of Narcotics and Dangerous Drugs (DEA's predecessor) agreed and revised the regulatory language to "require knowledge" of a prescription's invalidity before a pharmacist can be found to have acted improperly in filling it. *Id.*

> An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person ***knowingly*** filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Id. at 7799 (emphasis added).

38. The rulemaking thus expressly chose to penalize only those pharmacists who knowingly fill illegitimate prescriptions.

39. Pharmacists are thus both required and permitted to fulfill their corresponding responsibility on a prescription-by-prescription basis by taking into account those factors that the pharmacist, in the exercise of sound professional judgment, deems relevant to whether the prescription is issued in the course of professional treatment.

40. According to the regulations, penalties can only be levied where the pharmacist knows that the prescription is illegitimate and elects to fill it anyway.

41. This makes sense. Pharmacists are not physicians. The education and training they receive is significantly different from that of physicians. Unlike physicians, pharmacists, with certain very limited and irrelevant exceptions, do not examine patients and do not take vital signs or medical histories, perform diagnostic tests, or do most of the other things physicians do when

diagnosing patients and determining appropriate courses of treatment. Pharmacists cannot and should not second-guess a physician's medical judgment that a prescription is appropriate for a patient.

42. As DEA has explained, there are "no definitive criteria laying out precisely what is legally permissible" for doctors prescribing and dispensing controlled substances." *Dispensing Controlled Substances for the Treatment of Pain*, 71 Fed. Reg. 52716, 52720 (Sept. 6, 2006). "[E]ach patient's medical situation is unique and must be evaluated based on the entirety of the circumstances." *Id.* at 52,719.

43. Thus, DEA recognizes that the appropriate prescription "can vary greatly from patient to patient." *Id.* "A particular quantity of a powerful schedule II opioid might be blatantly excessive for the treatment of a particular patient's mild temporary pain, yet insufficient to treat the severe unremitting pain of a cancer patient." *Id.* at 52,720.

44. DEA has acknowledged that its regulatory regime does not pursue prevention of diversion at the cost of preventing patients from receiving the medications they need or the medical judgment of physicians. Although preventing diversion is an important goal, DEA "takes just as seriously its obligation to ensure that there is no interference with the dispensing of controlled substances to the American public in accordance with the sound medical judgment of their physicians." *Id.* at 52,719-20.

45. According to DEA, the number of illegitimate prescriptions is extremely small. DEA previously determined that "the ***overwhelming majority*** of American physicians who prescribe controlled substances do so for legitimate medical purposes," and it is only an "***extremely small fraction*** of physicians who use their DEA registration to commit criminal acts or otherwise violate the CSA." *Id.* at 52,719 (emphases added).

46. During a 2014 hearing before the House Subcommittee on Oversight and Investigations of the Committee of Energy and Commerce, then-Deputy Assistant DEA Administrator Joseph Rannazzisi testified that "***99.5 percent*** of the prescribers . . . are not overprescribing." Tr. of Hearing before the Subcommittee on Oversight and Investigations of the Committee of Energy and Commerce, House of Representatives, One Hundred Thirteenth Congress (April 29, 2014), available at https://www.govinfo.gov/content/pkg/CHRG-113hhrg90923/html/CHRG-113hhrg90923.htm (emphasis added).

47. The regulatory regime thus serves the dual goals of preventing diversion and ensuring that Americans receive the medications their physicians prescribe. Whether—and in what amount—to prescribe controlled substances is a decision entrusted to the sound professional judgment of physicians based on individual patients' unique circumstances. Again, according to DEA itself, the "overwhelming majority" of physicians write legitimate prescriptions and the fraction of illegitimate prescriptions is "extremely small."

48. In this regulatory regime, pharmacists fulfill their corresponding responsibility by exercising professional judgment on a prescription-by-prescription basis. Penalties can be imposed only if a pharmacist fills a particular prescription for a controlled substance the pharmacist knows to be invalid.

III. Regulated Entities Design and Implement Diversion-Prevention Programs Consistent with the Regulations and DEA's Dual Goals.

49. Walgreens operates approximately 8,700 pharmacies across the United States.

50. At all times relevant to this Complaint, Walgreens pharmacies were registered with DEA to dispense Schedule II-V controlled substances.

51. As an entity that is lawfully licensed and authorized to dispense controlled substances, Walgreens is subject to the CSA and its implementing regulations.

52. In connection with its dispensing of controlled substances, Walgreens has implemented programs to minimize the risk of diversion. Consistent with the regulatory regime and applicable state law, these programs have appropriately emphasized (and relied on) the professional judgment of individual pharmacists. Walgreens' internal policies and procedures intended to prevent diversion have exceeded the regulatory requirements in many ways.

53. If DEA were to determine that Walgreens failed to comply with the CSA or its implementing regulations, Walgreens would risk severe civil (and potentially criminal) sanctions as well as the potential loss of its registration (and thus its ability to dispense controlled substances lawfully).

IV. Without Following Notice-and-Comment Rulemaking, DEA Has Adopted—and DOJ Has Enforced—New Rules that Alter the Regulatory Regime.

54. Federal agencies, like DEA, must comply with the APA.

55. DEA has adopted final legislative rules regulating pharmacists' (and pharmacies') dispensing duties under the CSA without complying with the APA's notice-and-comment requirements.

A. Contrary to the regulations, DEA has adopted a rule that pharmacists must resolve all "red flags" before dispensing any prescription drug.

56. DEA has adopted a rule requiring pharmacists to resolve what DEA labels "red flags" before dispensing a controlled substance and further requires that pharmacists must document the resolution of "red flags" regarding a prescription before filling the prescription (collectively, the "Resolve Red Flags Rule"). A "red flag" is purportedly an indicium that a prescription may be unsafe or medically inappropriate.

57. The Resolve Red Flags Rule constitutes final agency action because it marks "the 'consummation' of [DEA's] decisionmaking process." *Bennett v. Spear*, 520 U.S. 154, 178

(1997). It is not tentative or interlocutory and has been consistently enforced by DEA as a mandatory rule. *Id.*

58. The Resolve Red Flags Rule is a requirement from which legal obligations and potential severe criminal, civil, and administrative consequences can also flow.

59. The Resolve Red Flags Rule subjects a pharmacist to penalties under the CSA for filling a prescription even if the pharmacist does not know that a prescription was not issued in the course of professional treatment.

60. Thus, the Resolve Red Flag Rule effectively reverses the knowledge requirement of 21 C.F.R. § 1306.04(a) and imposes legal duties on pharmacists beyond those required by the CSA and the regulations. It revises the obligation of a pharmacist from a sanctionable duty not to dispense ***if*** the pharmacist knows a prescription ***is not valid*** to a duty not to dispense ***unless*** the pharmacist knows a prescription ***is valid*** (because the pharmacist has identified, resolved, and documented the resolution of all red flags).

61. By requiring pharmacists to resolve red flags and document that resolution before dispensing controlled substances, DEA has altered the regulatory requirements and has imposed the duty on pharmacists "to determine the legitimacy of a prescription" that DEA's predecessor rejected in notice-and-comment rulemaking in 1971. *Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970*, 36 Fed. Reg. 7776, 7777 (Apr. 24, 1971).

62. The Resolve Red Flags Rule is a requirement by which "obligations have been determined" and "from which legal consequences will flow." *Id.* In light of the severe potential civil and criminal penalties, this new rule places registrants like Walgreens in a "Catch-22," stuck between blocking otherwise legitimate prescriptions based on hard-and-fast criteria found nowhere

in validly promulgated regulations "or feared liability." *See Arizona v. Biden*, 40 F.4th 375, 387 (6th Cir. 2022).

63. DEA and DOJ have applied the Resolve Red Flags Rule in a way "that indicates it is binding" and have discussed it in "mandatory language." *Texas v. EEOC*, 933 F.3d 433, 441–42 (5th Cir. 2019). This new rule has the effect of "forc[ing] [Walgreens] either to alter its conduct, or expose itself to potential liability." *Id.*

64. DEA has never issued any rule or regulation through notice-and-comment rulemaking that imposes the obligations contained in the Resolve Red Flags Rule.

1. DEA has announced that pharmacists must resolve all "red flags" before dispensing a controlled substance.

65. DEA and DOJ's public statements demonstrate the existence of the new rule and its finality. A number of examples follow.

66. U.S. Attorney Sandra J. Hairston for the Middle District of North Carolina recently announced that pharmacists "have an independent responsibility to ensure that the prescriptions they fill are for a legitimate medical purpose." Press Release, Department of Justice, Court Orders North Carolina Pharmacy to Pay $500,000 Penalty and Enters Injunction to Prevent Filling Illegal Controlled Substance Prescriptions (Dec. 6, 2024), https://www.justice.gov/opa/pr/court-orders-north-carolina-pharmacy-pay-500000-penalty-and-enters-injunction-prevent.

67. "'Pharmacies and pharmacists have an affirmative legal duty to ensure that the prescriptions they fill are legitimate,' said U.S. Attorney Rebecca C. Lutzko for the Northern District of Ohio." Press Release, Department of Justice, Rite Aid Corporation and Affiliates Agree to Settle False Claims Act and Controlled Substance Act Allegations Related to Opioid Dispensing (July 10, 2024), https://www.justice.gov/opa/pr/rite-aid-corporation-and-affiliates-agree-settle-false-claims-act-and-controlled-substance. Ms. Lutzko further asserted that pharmacies and

pharmacists violate this duty by "ignor[ing] red flags." *Id.*; *see also id.* (quoting DEA Administrator Anne Milgram alleging that Rite Aid "ignor[ed] obvious red flags").

68. "'A pharmacist must resolve all 'red flags' before the dispensation of any prescription drugs,' said Special Agent in Charge Daniel Comeaux of the Drug Enforcement Agency (DEA) Houston Division." Press Release, Drug Enforcement Administration, Federal Court Orders San Antonio-Area Pharmacy and Pharmacist to Pay $275,000 Civil Penalty in Case Alleging Unlawful Opioid Distribution (Oct. 11, 2023), https://www.dea.gov/press-releases/2023/10/11/federal-court-orders-san-antonio-area-pharmacy-and-pharmacist-pay-275000.

69. A "[pharmacists'] responsibility includes addressing and resolving 'red flags', that is, indications that a particular prescription may be unsafe or medically inappropriate, by obtaining additional information before filling the prescription." Press Release, Drug Enforcement Administration, Ferry County Hospital District Agrees to Pay $15,000 Penalty and Implement Corrective Actions to Address Improper Opioid Dispensing Practices at Republic Pharmacy (Oct. 2, 2023), https://www.dea.gov/press-releases/2023/10/02/ferry-county-hospital-district-agrees-pay-15000-penalty-and-implement.

70. "When pharmacists ignore 'red flags,' their dispensing contributes to the opioid epidemic. We at the DEA are working hard, every day, to investigate such behavior, and keep our communities safe." Press Release, Drug Enforcement Administration, Consent Decree Approved Between the United States and Baltimore-Based Pharmacy and Pharmacist Alleged to Have Illegally Dispensed Controlled Substances (May 12, 2022), https://www.dea.gov/press-releases/2022/05/12/consent-decree-approved-between-united-states-and-baltimore-based (quoting Jarod A. Forget, Special Agent in Charge of the Washington Division).

71. "Truong ignored and failed to resolve red flags, in violation of her responsibility as a pharmacist." Press Release, Drug Enforcement Administration, Local Pharmacist Pleads Guilty to Unlawful Distribution of Oxycodone (Apr. 27, 2020), https://www.dea.gov/press-releases/2020/04/27/local-pharmacist-pleads-guilty-unlawful-distribution-oxycodone.

72. "Pharmacies and their pharmacists have the responsibility to flag suspicious prescriptions written by doctors for highly sought after opioid medications, in order to prevent them from being dispensed." Press Release, Department of Justice, Federal Court Restrains Tampa Pharmacy and Two Individuals From Dispensing Opioids or Other Controlled Substances (Jan. 29, 2021), https://www.justice.gov/opa/pr/federal-court-restrains-tampa-pharmacy-and-two-individuals-dispensing-opioids-or-other. Pharmacies must "resolve red flags and ***ensure the legitimacy of prescriptions*** before filling them." *Id.* (emphasis added).

73. "Pharmacist and Pharmacy Ignored Red Flags Indicating Prescriptions were Not Legitimate, Including Filling Controlled Substances Prescriptions for Over 300 Patients that Traveled more than 180 Miles to the Pharmacy." Press Release, Drug Enforcement Administration, The United States and Montgomery County Based Pharmacy and Pharmacist Reach a Consent Decree Over Allegations of Illegally Dispensed Controlled Substances (May 31, 2023), https://www.dea.gov/press-releases/2023/05/31/united-states-and-montgomery-county-based-pharmacy-and-pharmacist-reach.

2. DEA and DOJ have consistently enforced DEA's Resolve Red Flag Rule.

74. DEA and DOJ have filed recent enforcement actions alleging violations of Resolve Red Flags Rule, which demonstrate that the rule exists, its scope, and the potentially serious consequences that flow from non-compliance.

75. In *United States v. Walmart Inc.*, 1:99-mc-09999, (D. Del. 2020), DOJ alleged that Walmart violated "rules requiring it to scrutinize controlled-substance prescriptions to ensure that they were valid." Dkt. 1446, ¶6. "These rules required Walmart to recognize, investigate, and resolve signs of a prescription's invalidity—'red flags[.]'" Dkt. 1446, ¶6. According to DOJ, "Walmart was well aware of these rules." *Id.*

76. The *Walmart* complaint succinctly summarized the rule: Pharmacists have a duty "[to] identif[y] and attemp[t] to resolve red flags; to document the resolution if the red flag is resolved; and to refuse to fill the prescription if the red flag is not resolved." *Id.*, ¶ 78.

77. In *United States v. Rite Aid Corporation*, 1:21-cv-01239 (N.D. Oh. 2021), DOJ alleged that pharmacists violated the CSA by "fill[ing] prescriptions for controlled substances that had obvious, and often multiple, red flags" and by "ignore[ing] these red flags, making either no effort or a patently inadequate effort to resolve the red flags." Dkt. 38., ¶ 7.

78. A complaint recently unsealed against CVS reiterates DOJ and DEA's new rules, alleging that "before filling a controlled substance prescription," pharmacists must: "(1) Identify red flags of illegitimacy; (2) Resolve any red flags of illegitimacy; and (3) Document the basis for filling the prescription." *United States v. CVS Pharmacy Inc.*, 1:22-cv-00222, Complaint, Dkt. 52, ¶ 45 (D. R.I. Dec. 13, 2024).

79. DOJ has also obtained injunctions and penalties in enforcement actions based on this rule.

80. One such case is *United States v. Beckman's Green Street Pharmacy, Inc.*, 1:23-cv-01630-LKG (D. Md. 2023). There, an injunction "prohibits the defendants from filling certain 'red flag' prescriptions and requires the defendants to fill other prescriptions only with documentation justifying those prescriptions." Press Release, Department of Justice, Court Orders

Maryland Pharmacy to Pay $120,000 Penalty in Case Alleging Unlawful Opioid Distribution, (July 6, 2023), https://www.justice.gov/opa/pr/court-orders-maryland-pharmacy-pay-120000-penalty-case-alleging-unlawful-opioid-distribution.

81. As the government set out in its complaint in the *Beckman's* case:

> To determine a prescription's legitimacy, a pharmacist must decide whether it presents 'red flags,' or warning signs that create a reasonable suspicion that the prescription is not legitimate or may be abused or diverted. "Red flags" may include, among other things, the amount of controlled substances prescribed; the combination of controlled substances prescribed; the abuse potential of those controlled substances; whether the patient seeks to pay cash for a controlled substance despite the availability of insurance coverage; whether the patient seeks to refill a controlled substance prescription early; and whether the patient has travelled unreasonably long distances to the prescriber or the pharmacy.

Dkt. 1, ¶ 21.

82. "When a 'red flag' is present," the government's complaint continued, "a pharmacist must conduct further and sufficient inquiry to determine whether the prescription for a controlled substances is legitimate." *Id.*, ¶ 22. A pharmacist who fills a prescription in the face of one or more red flags without taking sufficient steps to resolve the red flags exceeds that pharmacist's authorization to dispense controlled substances under the CSA and subjects the pharmacist and the pharmacy to civil penalties." *Id.*

3. The public recognizes that DEA has adopted the Resolve Red Flags Rule to govern pharmacy conduct.

83. Regulated entities—including the pharmacy industry generally—now recognize that DEA has adopted and enforces the Resolve Red Flags Rule, despite its absence from the regulations and the lack of formal DEA guidance.

84. Although DEA's adoption of the Resolve Red Flags Rule is widely recognized by the public, DEA has attempted to avoid formal announcement of the new rule in order to avoid

legal challenges. This approach denies the public the transparency required by the APA and frustrates the policy purposes underlying the requirement of notice-and-comment rulemaking.

85. This widespread understanding that the rule has been adopted and that it constitutes final agency action with enforcement consequences flowing from it is evidenced by numerous public statements and pharmacist training programs that have identified DEA as adopting and enforcing the Resolve Red Flags Rule.

86. One continuing education article for pharmacists explains: "It is the pharmacist's duty to investigate further and resolve red flags prior to dispensing; repeated failure to do so has resulted in disciplinary actions against individual pharmacists and pharmacies." Legal Obligations and Implications of Prescription Opioid Abuse: *Pharmacists' Role and Responsibilities,* PowerPak C.E., https://www.powerpak.com/courses/113842/Section2.aspx.

87. "[DEA] will inspect pharmacies that fail to recognize and address suspicious prescriptions for controlled substances (CS). Dispensers that ignore these 'red flag' prescriptions subject their licenses, their pharmacies and themselves to DEA and state enforcement action, a CS compliance expert noted during APhA2023." Prescribing Red Flags: What's a Pharmacist to Do?, David Bronstein (Mar. 28, 2023), https://www.pharmacypracticenews.com/Online-First/Article/03-23/Prescribing-Red-Flags-What%E2%80%99s-a-Pharmacist-to-Do/69871; *see also* https://www.painmedicinenews.com/Policy-and-Management/Article/08-23/Opioid-Red-Flags-Miss-Them-and-DEA-May-Come-Calling/71426?ses=ogst.

88. "Where red flags are present, a pharmacy must resolve the red flag before dispensing the prescription in question. As highlighted by recent DOJ actions, a failure to do so could subject pharmacies to discipline such as losing the ability to dispense opioids and other controlled substances. . . . Pharmacies must also ensure that they are keeping proper records and

documentation which indicate the pharmacy's recognition of a red flag and the proactive measures it took to resolve red flags." Pharmacy Alert: Recognizing and Resolving Red Flags when Dispensing Opioids, Dae Y. Lee, Pharm.D., Esq., CPBS and Adam Farkas, Esq., Frier Levitt (May 3, 2022), https://www.frierlevitt.com/articles/pharmacy-alert-recognizing-and-resolving-red-flags-when-dispensing-opioids/.

89. The public understands that the Resolve Red Flags Rule reflects legal obligations DEA will enforce.

4. The Resolve Red Flags Rule imposes new duties on regulated parties and adds content to legal norms.

90. The Resolve Red Flags Rule constitutes a legislative rule for purposes of the APA.

91. The Resolve Red Flags Rule "impose[s] new . . . duties" on regulated parties. *Mann Constr., Inc. v. United States*, 27 F.4th 1138, 1143 (6th Cir. 2022). It "adds content to the governing legal norms" regarding dispensing controlled substances, *Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 96 (D.C. Cir. 1997), and "effects a substantive regulatory change to the statutory or regulatory regime." *Mendoza v. Perez*, 754 F.3d 1002, 1021 (D.C. Cir. 2014).

92. While the regulations rely on pharmacists' professional judgment in exercising their corresponding responsibility on a prescription-by-prescription basis and only penalize pharmacists who "knowingly fil[l]" invalid prescriptions, 21 C.F.R. § 1306.04(a), the Resolve Red Flags Rule imposes new duties on pharmacists, including to "ensure the legitimacy of prescriptions before filling them." Press Release, Department of Justice, Federal Court Restrains Tampa Pharmacy and Two Individuals From Dispensing Opioids or Other Controlled Substances (Jan. 29, 2021), https://www.justice.gov/opa/pr/federal-court-restrains-tampa-pharmacy-and-two-individuals-dispensing-opioids-or-other.

93. This new rule makes substantives changes to the CSA's implementing regulations. The Resolve Red Flags Rule effectively reverses the obligation of a pharmacist, transforming it from a duty not to dispense ***if*** the pharmacist ***knows*** the prescription ***is not valid*** into a duty to not dispense ***unless*** the pharmacist determines the prescription ***is valid*** (because the pharmacist has identified, resolved, and documented the resolution of any red flags).

94. "Because interpretive rules cannot effect a substantive change in the regulations, a rule that adopts a new position inconsistent with any of the [agency's] existing regulations is necessarily legislative." *Tenn. Hosp. Ass'n v. Azar*, 908 F.3d 1029, 1042 (6th Cir. 2018).

95. Registered entities like Walgreens face the risk of serious criminal and civil penalties and potential loss of DEA registration if their pharmacists fail to comply with the Resolve Red Flags Rule.

B. Without any support in the regulations, DEA has adopted a rule that pharmacies must block certain prescribers and refuse to fill any controlled substance prescriptions issued by them.

96. DEA also has adopted a rule that pharmacies must block particular prescribers and refuse to allow any pharmacist employee to fill any prescription from such prescribers, without regard to the validity or invalidity of the individual prescriptions (the "Block Prescribers Rule").

97. The Block Prescribers Rule constitutes the culmination of DEA's decision-making process. It is not tentative or interlocutory.

98. DEA has never issued any rule or regulation through notice-and-comment rulemaking that imposes obligations with respect to a pharmacy's duties to block particular prescribers and to refuse to fill any controlled substance prescriptions issued by them.

99. The Block Prescribers Rule constitutes final agency action because is a requirement from which legal obligations and consequences flow. Registered entities like Walgreens risk

serious civil, criminal, and administrative penalties unless they comply with the Block Prescribers Rule.

100. In *United States v. Rite Aid*, DOJ alleged that "even where Rite Aid's Government Affairs Department knew that a practitioner was not prescribing controlled substances for legitimate medical purposes through reports from its own pharmacists, Rite Aid very rarely took action to stop the flow of opioids prescribed by that practitioner." 1:21-cv-01239, Dkt. 38, ¶ 12. DOJ further alleged that filling any prescription from these prescribers was "unlawful" because the prescriptions were "issued by prescribers who . . . Rite Aid [(not the individual pharmacist)] knew to be suspicious and to issue unlawful prescriptions to patients." *Id.*, ¶ 91.

101. DEA and DOJ reiterated this rule in a press release, arguing that prescriptions were "unlawful" (and violated the CSA) because they were "issued by prescribers who [pharmacists] had repeatedly identified internally as suspicious and as writing unlawful, unnecessary prescriptions." Press Release, Department of Justice, Rite Aid Corporation and Affiliates Agree to Settle False Claims Act and Controlled Substance Act Allegations Related to Opioid Dispensing (July 10, 2024), https://www.justice.gov/opa/pr/rite-aid-corporation-and-affiliates-agree-settle-false-claims-act-and-controlled-substance. According to DEA and DOJ, the Block Prescribers Rule mandates that if a prescriber is "suspicious" and has written "unlawful, unnecessary prescriptions," then filling ***any*** subsequent prescription from the prescriber is unlawful, even if the prescriber is duly licensed by the relevant state medical board and has an active DEA registration to issue prescriptions for controlled substances.

102. The Block Prescribers Rule constitutes a legislative rule for purposes of the APA.

103. The Block Prescribers Rule "impose[s] new . . . duties" on regulated parties. *Mann Constr., Inc. v. United States*, 27 F.4th 1138, 1143 (6th Cir. 2022). It "ad[ds] content to the

governing legal norms" regarding dispensing controlled substances, *Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 96 (D.C. Cir. 1997), and "effects a substantive regulatory change to the statutory or regulatory regime." *Mendoza v. Perez*, 754 F.3d 1002, 1021 (D.C. Cir. 2014).

C. By altering the regulatory regime without proceeding through notice-and-comment rulemaking, DEA has deprived itself of important feedback from important stakeholders and the public.

104. The proper dispensing of controlled substances and the balance between the responsibilities of physicians and pharmacists are issues of great public importance.

105. In the wake of the opioid crisis, interested stakeholders undoubtedly have important views on the issues implicated by these new rules. It is the purpose of notice-and-comment rulemaking to ensure that these views are taken into account.

106. Organizations such as the American Medical Association ("AMA"), state medical and pharmacy boards, other government agencies, trade associations, and the pharmacy industry, among others, all have valuable perspectives on the proper duties of physicians and pharmacists and whether pharmacists should be required to verify the legitimacy of controlled substance prescriptions (by resolving red flags and documenting the resolution of such red flags) before filling them and whether pharmacies should be required to block prescribers without regard to the validity of individual prescriptions for controlled substances.

107. For example, physicians have long complained to state medical boards about pharmacists intruding on the practice of medicine. AMA Meeting: Pharmacists Warned on Intruding into Prescribing Decisions, AMERICAN MEDICAL NEWS (July 1, 2013).

108. The AMA adopted a resolution, widely referred to in the pharmacy industry as the "don't call us, we'll call you" resolution, rejecting "inappropriate inquiries from pharmacies to verify the medical rationale behind prescriptions" as "interference with the practice of medicine." AMA Resolution 218 (2013).

109. The Centers for Disease Control and Prevention rejects "hard limits" on opioid prescriptions: "[P]olicies that mandate hard limits conflict with the Guideline's emphasis on individualized assessment of the benefits and risks of opioids given the specific circumstances and unique needs of each patient." CDC Advises Against Misapplication of the Guideline for Prescribing Opioids for Chronic Pain, available at https://www.cdc.gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html.

110. DEA also needs to account for state regulations and consider whether the rules it adopts pose potential conflicting obligations for pharmacists. For example, Section 733 of California's Business and Professionals Code contains a "shall dispense" provision: "No licentiate shall obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient," unless the circumstances fall within limited exceptions set forth in the statute.

111. By adopting its new rules without following the notice-and-comment process required by the APA, DEA has deprived itself (and the public) of the critical opportunity for comment that the APA requires. Had DEA followed the required notice-and-comment process, perhaps it could have avoided promulgating new rules which, as outlined below, are arbitrary and capricious.

V. DEA's New Rules Are Arbitrary and Capricious.

112. Not only did DEA fail to comply with the APA's procedural requirement of notice-and-comment rulemaking, but the rules it has adopted are arbitrary and capricious. 5 U.S.C. § 706(2)(A).

113. "[A]n agency rule [is] arbitrary and capricious if the agency has . . . entirely failed to consider an important aspect of the problem [or] offered an explanation for its decision that runs

counter to the evidence before the agency." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

114. An agency also acts arbitrarily and capriciously when it "chang[es] its course" without "supply[ing] a reasoned analysis for the change." *Id.* at 42. "[T]he requirement that an agency provide reasoned explanation for its action would ordinarily demand that it display awareness that it **is** changing position. An agency may not, for example, depart from a prior policy *sub silentio* or simply disregard rules that are still on the books." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

115. In adopting the Resolve Red Flags Rule, DEA failed to consider the need to "ensure that there is no interference with the dispensing of controlled substances to the American public in accordance with the sound medical judgment of their physicians." *Dispensing Controlled Substances for the Treatment of Pain*, 71 Fed. Reg. at 52,719-20 (Sept. 6, 2006).

116. By requiring that pharmacists "resolve red flags and ***ensure the legitimacy of prescriptions*** before filling them," Press Release, Department of Justice, Federal Court Restrains Tampa Pharmacy and Two Individuals From Dispensing Opioids or Other Controlled Substances (Jan. 29, 2021), https://www.justice.gov/opa/pr/federal-court-restrains-tampa-pharmacy-and-two-individuals-dispensing-opioids-or-other (emphasis added), DEA's new rule significantly interferes with the dispensing of controlled substances to the American public in accordance with the medical judgment of their physicians. In adopting the Resolve Red Flags Rule, DEA failed to consider this important aspect of the problem.

117. Nor did DEA consider that its new rules require pharmacists to second-guess the medical judgment of physicians, a violation of various state laws. The President of the Texas Medical Board threatened cease-and-desist orders against pharmacists for interfering in the

practice of medicine by not filling certain opioid prescriptions. *See, e.g.*, Sherif Zaafran, MD (@szaafran), Twitter (Sept. 29, 2018, 11:29 pm), https://twitter.com/szaafran/status/1046240520786378752 (President of the Texas Medical Board) (stating that pharmacies would engage in "the unlicensed practice of medicine" by "putting out guidelines to change amounts of opioids prescribed").

118. Patients themselves have sued pharmacists and pharmacies for refusing to fill facially valid prescriptions, both in individual suits and in class action lawsuits under the Americans with Disabilities Act and analogous state laws. *See, e.g.*, *Smith v. Walgreens Boots All., Inc.*, No. 3:20-cv-05451-JD (N.D. Cal. Aug. 6, 2020) (putative class action alleging "corporate wide discriminatory practices in refusing to fill, without a legitimate basis, valid and legal prescriptions for opioid medication"); *Fuog v. CVS Pharmacy, Inc.*, No. 1:20-cv-00337-WES-LDA (D.R.I. Aug. 6, 2020) (similar); *Bruno v. Walmart Stores, Inc.*, No. 19CV000053 (Wis. Cir. Ct. May 3, 2019); *Thomas v. Walmart Inc.*, No. 19CY-CV02460 (Mo. Cir. Ct. Mar. 8, 2019). DEA failed to consider these state duties in adopting its new rules.

119. DEA also failed to consider its own findings that the "the overwhelming majority of American physicians who prescribe controlled substances do so for legitimate medical purposes" and that only an "extremely small fraction of physicians" violate the CSA. *Dispensing Controlled Substances for the Treatment of Pain*, 71 Fed. Reg. at 52,719. Evaluating the appropriate duties of pharmacists must account for the extreme rarity of invalid prescriptions.

120. Such an analysis must also consider DEA's control over the aggregate quantity of controlled substances. DEA sets aggregate production quotas and individual manufacturing quotas for each registrant manufacturing Schedule I or II drugs. 21 U.S.C. §826(b); 21 C.F.R. § 1303.12. As a result, the total volume of a Schedule I or II drug manufactured and dispensed necessarily

reflects—and always has reflected—DEA's considered judgment about the appropriate aggregate need for the drug. In determining whether new duties should be imposed on pharmacies and pharmacists, DEA should have considered the other controls at its disposal to limit the quantities of Schedule I and Schedule II drugs available.

121. Moreover, DEA's new rule that pharmacists "ensure the legitimacy of prescriptions" by resolving red flags conflicts with the decision of the Bureau of Narcotics and Dangerous Drugs ***not*** to require a pharmacist "to determine the legitimacy of a prescription." *Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970*, 36 Fed. Reg. 7776, 7777 (Apr. 24, 1971). DEA has changed its position regarding pharmacists' duties without an explanation for the change (or even, apparently, awareness of the change).

122. In adopting the Block Prescribers Rule, DEA also failed to consider state pharmacy laws, which may forbid pharmacies from refusing to fill prescriptions from a prescriber without regard to the legitimacy of the particular prescription. For example, the Idaho Deputy Attorney General told Walmart by letter that a policy of blocking prescribers at the corporate level would "preven[t] pharmacists from fulfilling their legal obligations . . . and from exercising their obligation of corresponding responsibility." Letter from Steven L. Olsen, Idaho Deputy Attorney General, to Idaho Wal-Mart Pharmacies (Feb. 8, 2019). Similarly, the Wisconsin Pharmacy Examining Board threatened Walmart with disciplinary action when a pharmacy told a local clinic that it "would no longer fill controlled substance prescriptions from that clinic" because "[t]he broad prohibition . . . deterred pharmacists . . . from exercising their independent clinical judgment." Wisconsin Pharmacy Examining Board, Administrative Warning, Division of Legal Services and Compliance Case No. 17 PHM 095 (Dec. 6, 2018).

123. Indeed, pharmacies and pharmacists have been sued for blocking prescribers and for allegedly defaming prescribers by including notes about them. *See, e.g.*, *Yarus v. Walgreen Co.*, 738 F. App'x 94 (3d Cir. 2018) (defamation suit against Walgreens for statements in prescriber profile); *Mimms v. CVS Pharmacy, Inc.,* 889 F. 3d 865 (7th Cir. 2018); *Goulmamine v. CVS Pharmacy, Inc.*, No. 3:15-cv-00370 (E.D. Va.); *Richardson v. CVS Caremark Corp.*, No. 1:18 CV 1308 (N.D. Ohio); *Kahn v. Ariz. CVS Stores LLC*, No. 1 CA-CV 16-0333 (Ariz. Ct. App. Feb. 14, 2017); *Bonner v. Rite Aid Corp.*, No. 19CV00674MCEEFB (E.D. Cal.) (suit by pain management specialist against Rite Aid for defamation); *Hartman v. Rite Aid Corp.*, No-2016-00768 (Ct. Common Pleas, Lebanon Cty., PA); *Reasor v. Walmart Stores E., L.P.*, No. 3:19-CV-27-CRS (W.D. Ky.); *Lefrock v. Walgreens Co.*, No. 13–cv–02196 (M.D. Fla.); *Sultan v. Walgreen Co.,* 324 So. 3d 563 (Fla. Dist. Ct. App. 2021).

124. DEA also failed to consider whether imposing a duty on pharmacies to block prescribers is warranted in light of its own ability to revoke the registration of physicians who prescribe improperly. 21 U.S.C. §§ 824(a)(4), 823(f). DEA failed to consider that it is far better equipped than any pharmacy to investigate a prescriber and, by revoking a registration, can block ***all*** prescriptions for controlled substances from that prescriber from any pharmacy in the United States.

125. Most significantly, DEA failed to acknowledge (much less explain) its change from a system that focused on individual prescriptions and the knowledge and professional judgment of the individual pharmacist to a system imposing blanket duties on pharmacies related to prescribers. The CSA's implementing regulations govern the conduct of individual pharmacists filling individual prescriptions. In contrast, the Block Prescribers Rule imposes duties on pharmacies unrelated to the validity of any individual prescription.

126. DEA has previously explained that the test for validity must be flexible because there are "no definitive criteria laying out precisely what is legally permissible" for doctors prescribing and dispensing controlled substances." *Dispensing Controlled Substances for the Treatment of Pain*, 71 Fed. Reg. 52716, 52720 (Sept. 6, 2006). "[E]ach patient's medical situation is unique and must be evaluated based on the entirety of the circumstances." *Id.*

127. In contrast, the Block Prescribers Rule prevents evaluation of an individual patient's medical situation or the validity of an individual prescription and requires instead that pharmacies refuse to fill any controlled substance prescriptions from certain prescribers, valid or invalid.

128. Like the Resolve Red Flags Rule, the Block Prescribers Rule significantly interferes with the "dispensing of controlled substances to the American public in accordance with the sound medical judgment of their physicians," an important aspect of the problem that DEA failed to consider in adopting the rule.

CAUSES OF ACTION
COUNT I
DEA - Resolve Red Flags Rule
Agency Action Without Procedure Required by Law
5 U.S.C. § 706(2)(D)

129. The allegations in Paragraphs 1-128 are reincorporated herein.

130. A court shall "hold unlawful and set aside agency action . . . found to be . . . without observance of procedure required by law." 5 U.S.C. § 706(2)(A).

131. DEA's adoption of the Resolve Red Flags Rule constitutes final agency action subject to judicial review. 5 U.S.C. § 704.

132. The Resolve Red Flags Rule constitutes a legislative rule, which the APA requires to be adopted through notice-and-comment rulemaking. 5 U.S.C. § 553(b).

133. Because DEA did not adopt the Resolve Red Flags Rule though notice-and-comment rulemaking, it is unlawful and must be "set aside." 5 U.S.C. § 706(2).

COUNT II
DEA - Resolve Red Flags Rule
Arbitrary and Capricious Agency Action
5 U.S.C. § 706(2)(D)

134. The allegations in Paragraphs 1-133 are reincorporated herein.

135. A court shall "hold unlawful and set aside agency action . . . found to be arbitrary, capricious, [or] an abuse of discretion." 5 U.S.C. § 706(2)(A).

136. In adopting the Resolve Red Flags Rule, DEA failed to consider important aspects of the problem, failed to acknowledge that this new requirement constitutes a change in position, and failed to provide an adequate explanation for the change.

137. Because the Resolve Red Flags Rule is arbitrary and capricious, it is unlawful and must be "set aside." 5 U.S.C. § 706(2).

COUNT III
DEA - Block Prescribers Rule
Agency Action Without Procedure Required by Law
5 U.S.C. § 706(2)(D)

138. The allegations in Paragraphs 1-137 are reincorporated herein.

139. A court shall "hold unlawful and set aside agency action . . . found to be . . . without observance of procedure required by law." 5 U.S.C. § 706(2)(A).

140. DEA's adoption of the Block Prescribers Rule constitutes final agency action subject to judicial review. 5 U.S.C. § 704.

141. The Block Prescribers Rule constitutes a legislative rule, which the APA requires to be adopted through notice-and-comment rulemaking. 5 U.S.C. § 553(b).

142. Because DEA did not adopt the Block Prescribers Rule though notice-and-comment rulemaking, it is unlawful and must be "set aside." 5 U.S.C. § 706(2).

COUNT IV
DEA - Block Prescribers Rule
Arbitrary and Capricious Agency Action
5 U.S.C. § 706(2)(D)

143. The allegations in Paragraphs 1-142 are reincorporated herein.

144. A court shall "hold unlawful and set aside agency action . . . found to be arbitrary, capricious, [or] an abuse of discretion." 5 U.S.C. § 706(2)(A).

145. In adopting the Block Prescribers Rule, DEA failed to consider important aspects of the problem, failed to acknowledge that this new requirement constitutes a change in position, and failed to provide an adequate explanation for the change.

146. Because the Block Prescribers Rule is arbitrary and capricious, it is unlawful and must be "set aside." 5 U.S.C. § 706(2).

COUNT VII
DEA and DOJ
Declaratory Judgment

147. The allegations in Paragraphs 1-146 are reincorporated herein.

148. The Resolve Red Flags Rule is unlawful because it is a legislative rule that did not undergo notice-and-comment rulemaking.

149. The Resolve Red Flags Rule is unlawful because it is arbitrary and capricious.

150. Accordingly, Walgreens is entitled to a declaration that the Resolve Red Flags Rule is invalid and cannot be enforced against Walgreens.

151. The Block Prescribers Rule is unlawful because it is a legislative rule that did not undergo notice-and-comment rulemaking.

152. The Block Prescribers Rule is unlawful because it is arbitrary and capricious.

153. Accordingly, Walgreens is entitled to a declaration that the Block Prescribers Rule is invalid and cannot be enforced against Walgreens.

REQUEST FOR RELIEF AND DEMAND FOR JUDGMENT

Walgreens respectfully requests the following relief:

A. A declaratory judgment holding unlawful the Resolve Red Flags Rule and the Block Prescribers Rule and holding that Walgreens is not bound by them.

B. A judgment setting aside the Resolve Red Flags Rule and Block Prescribers Rule.

C. A permanent injunction prohibiting Defendants and their officers, agents, servants, employees, attorneys, and any other persons who are in active concert or participation with those individuals from enforcing the Resolve Red Flags Rule and Block Prescribers Rule against Walgreens.

D. Reasonable attorneys' fees and costs to which Walgreens is entitled.

E. All other relief to which Walgreens may show itself to be justly entitled.

Dated: January 16, 2025

Respectfully submitted,

By: */s/ William R. Peterson*

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